



Study Title: An Emergency Department-Based Study to Reduce Adolescent Pregnancy Rates

Version Date: June 11th, 2019

Consent Name: Advanced Practice Providers

Principal Investigator: Dr. Cynthia Mollen Telephone: (215) 590-1944

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

Study Overview

You are being asked to take part in this study because you are an Advanced Practice Provider who has 6 months or more experience working in the Emergency Department.

The purpose of this research study is to help us understand why female adolescents may or may not initiate contraception after receiving a contraceptive counseling session.

The first part of this study will include two 4-hour training sessions. The second part of the study will last approximately 30 minutes during the Emergency Department visit of an eligible participant. If you agree to participate, you will be asked to complete:

- Identification of eligible patients during clinical patient encounters
- Two 4-hour training sessions to learn about contraceptive methods, interviewing techniques, and to address common questions
- A 10-15-minute contraceptive counseling session with an eligible patient
- A questionnaire to provide feedback on the counseling you completed
- A referral of the participant to an adolescent gynecologist, a hospital-affiliated adolescent clinic or to a local Title X funded for additional counseling and to initiate or follow-up

Taking part in this study involves a risk of breach of confidentiality. If you have questions about the possible risk listed below, you should talk to the study doctor. You will not benefit directly from participating in this study.

Participation in this study is voluntary. Participation will not be shared with your supervisor, and your decision to participate will not have any effect on your performance evaluation or employment status.

If you are interested in learning more about the study, please continue to read below.

In the sections that follow, the word “we” means the study doctor and other research staff.

What are the study procedures?

If you agree to this participate in this study, you will participate in two 4-hour training sessions, the first via webinar, and the second via an in-person interactive session to learn

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about contraceptive methods and interviewing techniques, and to address common questions. As part of training, you will perform counseling with mock patients, and be observed by experts in gynecological health and adolescent health, who will provide timely feedback after the first counseling session you perform. Counseling sessions completed with participants as a part of this study may also be recorded.

After training, you will identify potentially eligible patients during clinical patient encounters, and you will provide eligible, consented study participants with confidential contraceptive counseling sessions that will last about 10-15 minutes. After the counseling, you will complete a questionnaire to provide feedback on the counseling session.

As part of counseling, you will also refer participants to an adolescent gynecologist, a hospital-affiliated adolescent clinic, or a local Title X funded clinic (based on patient preference and access) for additional counseling and to initiate or follow-up on initiation, as applicable. You will share clinical information and contact the receiving site via an electronic medical record (EMR) message or phone call.

What will be done with my data during this study?

During the study, we will collect information from you regarding your participation in contraceptive counseling. By agreeing to participate in the study, you agree to share this data with CHOP for research purposes.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about the possible risk listed below, you should talk to the study doctor.

Risks of Breach of Privacy and Confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure your personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. The number will be used on data collection forms and in the database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

Your decision to participate will not be shared with your supervisor and will not have any effect on your performance evaluation or employment status. Additionally, your patients (and their parents) will not be aware of your responses to the questionnaire.

Are there any benefits to taking part in this study?

You may gain additional skills and knowledge from the contraceptive counseling training. The knowledge gained from this study may also help doctors better provide contraceptive services for Emergency Department teens in the future.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Your decision to participate (or not participate) in the research will not affect your performance evaluation or employment. The data you provide and your decision to participate or not participate will not be shared with your supervisors.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in this study in order to continue employment at CHOP. If you decided not to take part or if you change your mind later, there will be no effect on your performance evaluation or employment status.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information.

They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The Data Safety Monitoring Board (DSMB) who monitors the safety of this study;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury, or disability.
- The National Institutes of Health who is sponsoring this research.

By law, CHOP is required to protect your information. The research staff will only allow access to your information to the groups listed above. By giving your consent, you are authorizing CHOP to use and/or release your information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information could be shared for:

- other scientific research;
- your medical treatment

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Cynthia Mollen
The Children's Hospital of Philadelphia
Department of Emergency Medicine
34th Street and Civic Center Blvd.
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In the letter, state that you changed your mind and do not want any more of your information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

Financial Information

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions or concerns about this study or how your data is going to be used, call the study doctor, Dr. Cynthia Mollen at 215-590-1944.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What will be done with my data when this study is over?

We will use and may share data for future research. It may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

By signing this form, you are indicating that you have had your questions answered and you agree to take part in this research study. If you don't agree to the collection, use and sharing of information, you cannot participate in this study.

Name of Subject

Signature of Subject

Date